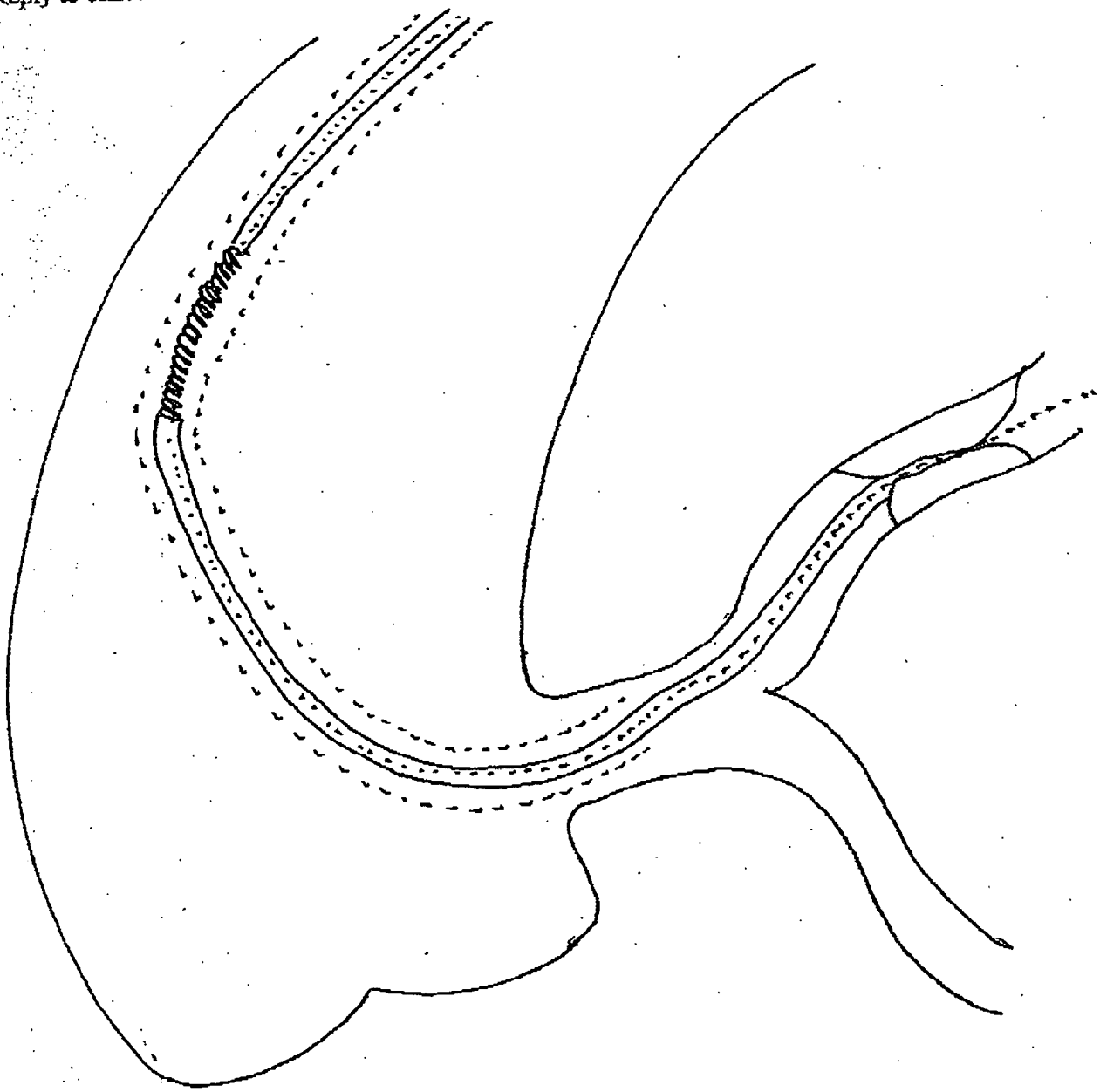

Exhibit Figure 5

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Application No 10/628,207
Application dated July 29, 2003
Reply to office action of 11th June 2010

Exhibit fig 3
Further push the assembly starts curving down. Further push will cause the guide wire and balloon to fall back

Exhibit fig 4
Balloon catheter where part of shaft is replaced by a spring is stuck at obstruction

Exhibit fig 5
Further push compresses the spring which helps in transmitting the force to distal end and alignment is maintained. It may move with a jump. Rotablator use has taught us that such jump is of no clinical consequence.

Above material is clearly written in the initial application except the exhibit figures. Exhibit figures were not required as any interventional cardiologist will understand this(push, buckling and alignment etc).

Continued on next page
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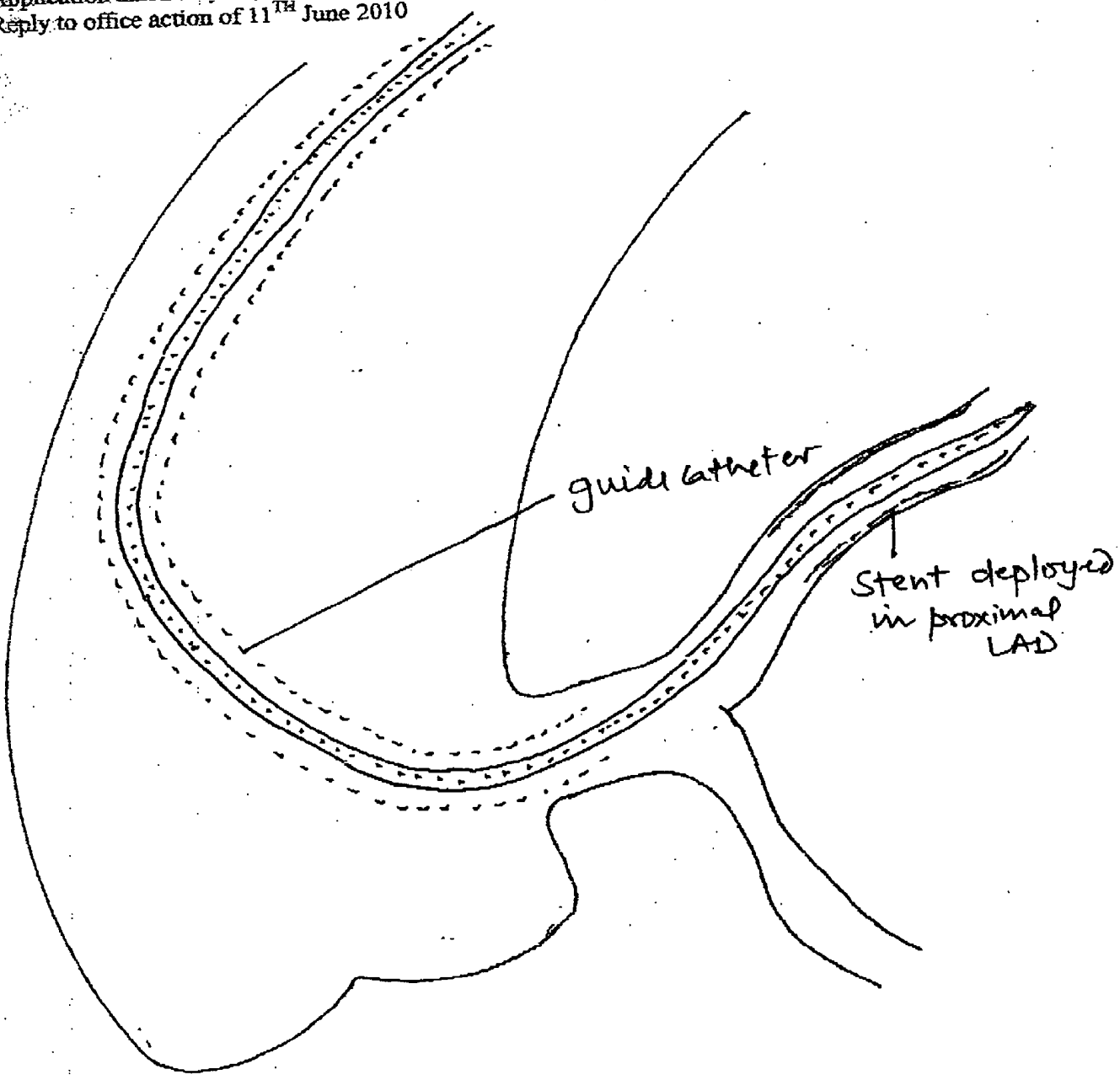

Exhibit Figure 6

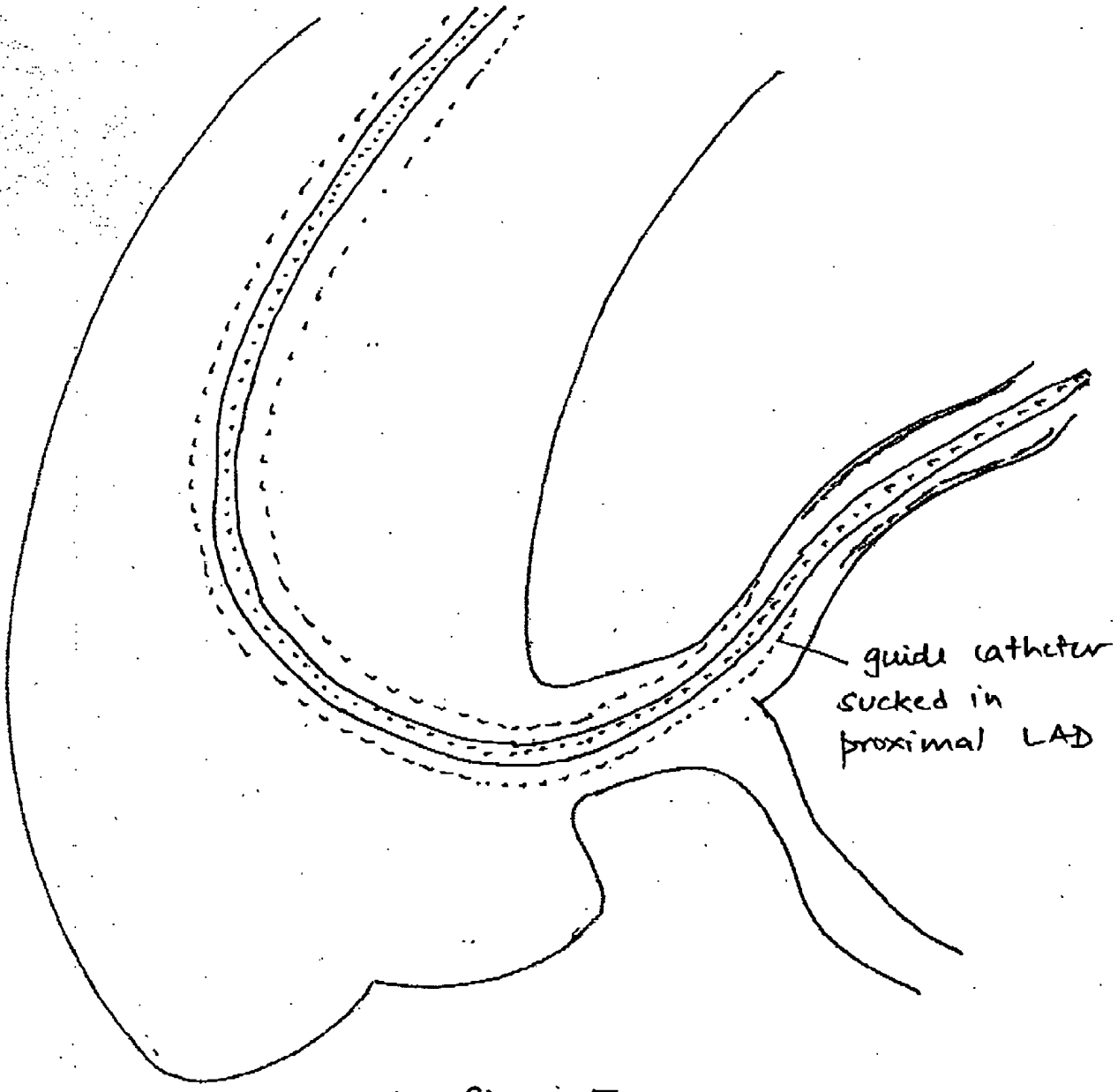

Exhibit figure 7

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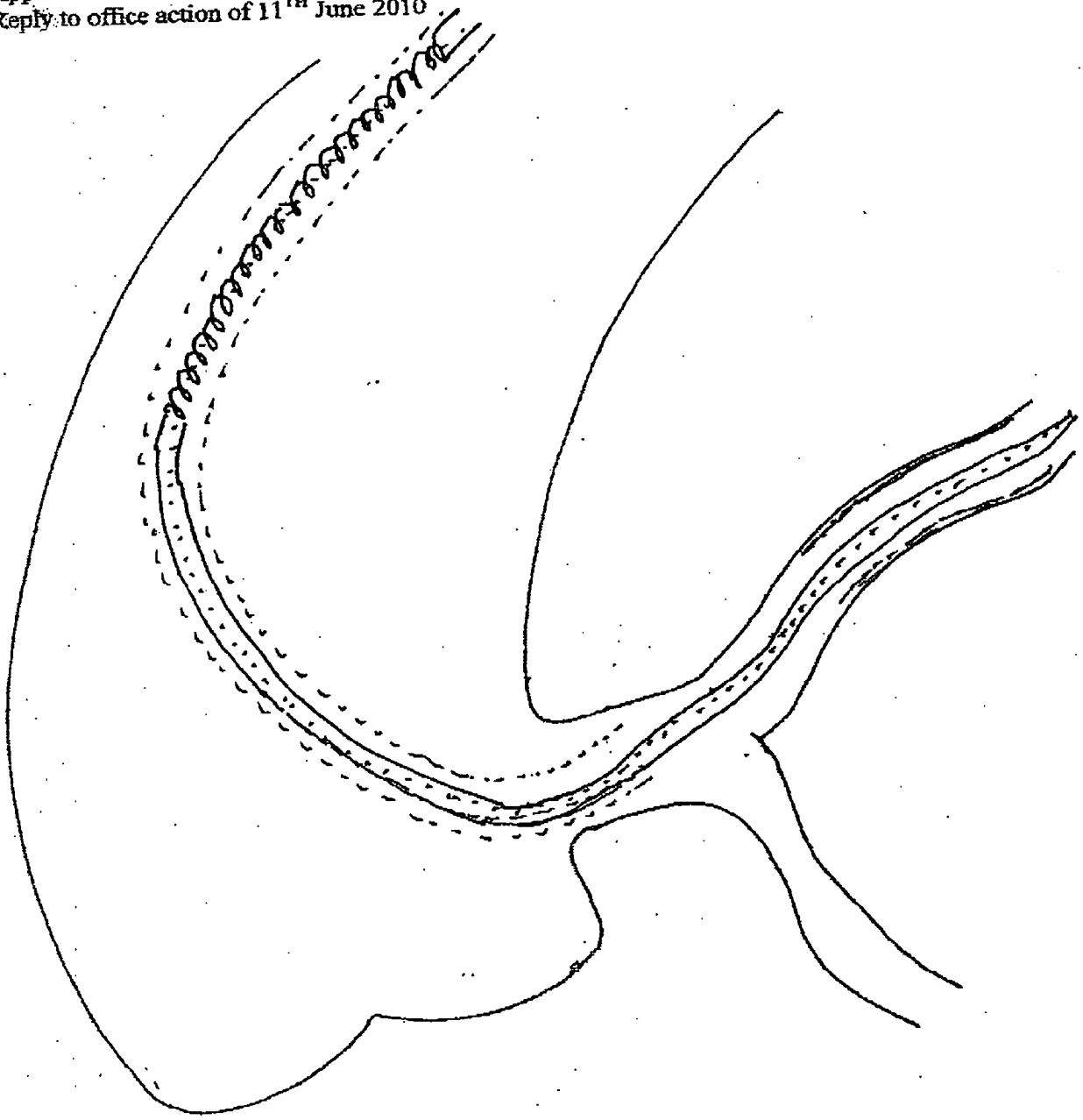

Exhibit Figure 8

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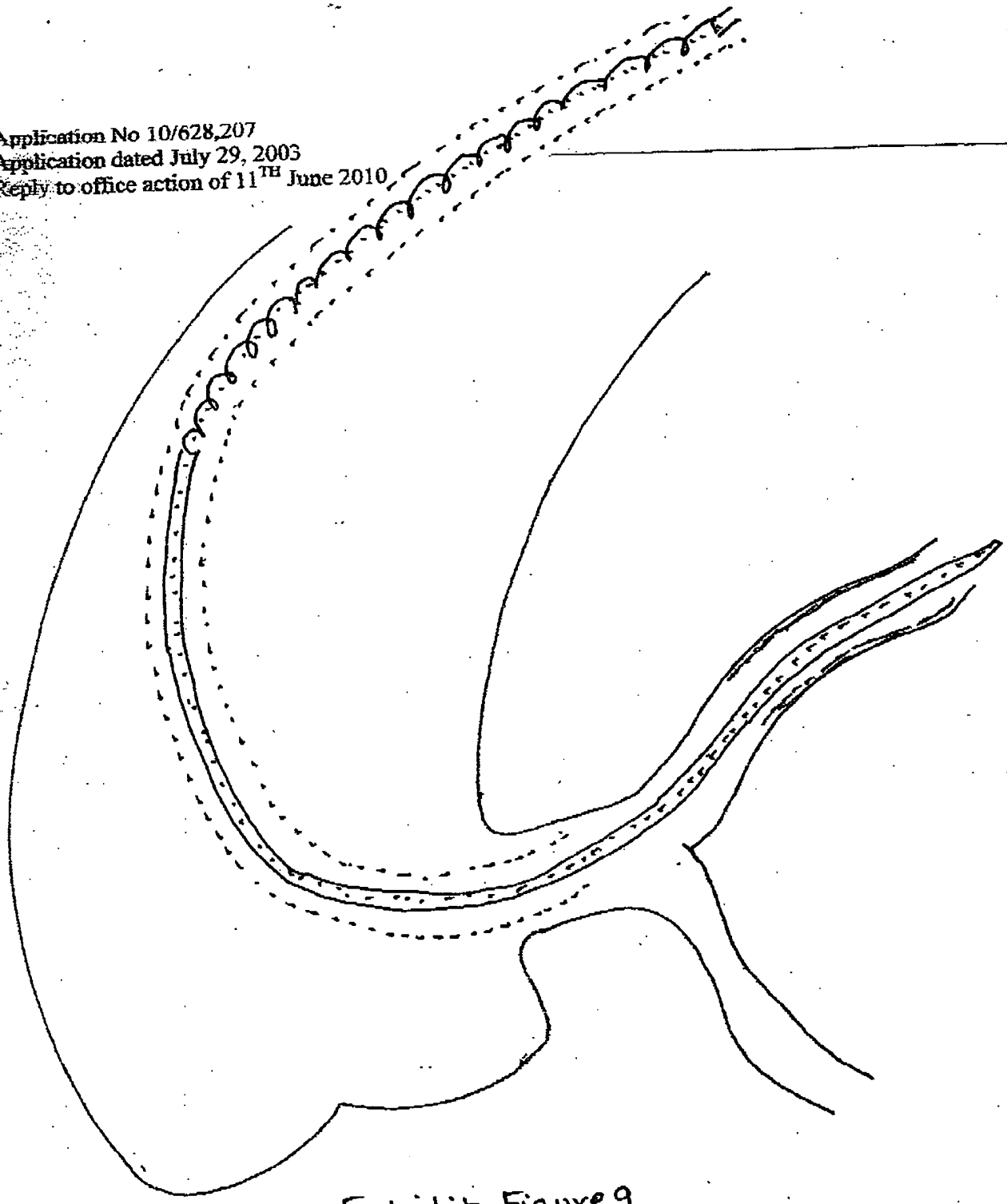

Exhibit Figure 9

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Often while pulling the balloon catheter back especially after deploying a coronary stent the guide catheter is sucked inside. The stent sometimes holds balloon and the length of balloon catheter is reduced inside the assembly, which causes guide catheter to be sucked inside. Normally it is of no consequence as the tip of guiding catheter is soft.
I learnt about an a case which happened with a colleague (note after filing this application) that the guide catheter when sucked inside dissected the left main which required a drug eluting stent. This is a serious complication as the patient now is a substrate with a DES in unprotected left main so has to be on life long high dose antiplatelets and its side effects and stent at left main bifurcation.
In a catheter with spring such complication will not occur as when balloon catheter is being pulled back the spring will increase in length so the total length of balloon catheter will not decrease inside the assembly and the guide catheter will not be sucked inside (unlike previous situation where pushing the catheter increased the length of balloon catheter inside the assembly and pushed guide catheter out of left main. With further push length of balloon catheter further increased in assembly and everything curved down and later fall back as push is increasing the length of balloon catheter in assembly).
Exhibit fig 6
Balloon catheter and guide catheter position after stent deployment

Exhibit fig 7
Balloon catheter being pulled and guide catheter gets sucked in proximal LAD
Exhibit fig 8
Catheter of current application after stent deployment
Exhibit fig 9
Catheter of current application after stent deployment. After pulling the balloon catheter, If stent is holding balloon the spring will lengthen and will maintain the pull. The guide catheter will not be sucked in proximal LAD as the length of balloon catheter is not reduced.
The matter on this page is not in specification as I learnt about that complication after filing application. I am writing about it just to explain you one more advantage and please ignore this as these details are not in specification filed earlier.

I will take this opportunity to inform you about a crude prototype
Took a PTCA guide wire and a fine electrical insulation wire like structure simulating PTCA balloon shaft (one long one divided into two)
One part I further cut and stitched a spring with prolene at either end
I used a PVC pipe to simulate the guiding catheter
Then I asked another person to cover both pieces by cloth and keep changing their position so that it becomes double blind.
Then I asked 3 independent persons to observe the push (forward force) in both

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Everyone observed that one with spring had more push.
Note that in a balloon catheter two lumens run
1 guide wire lumen,
2 balloon lumen
Note that I have explained that the spring will be in that part of shaft with guide wire, thus it covers both types of balloon(over the wire and rapid exchange) automatically.
The balloon lumen is no problem and can run spirally like coronary artery either inside the spring circumference or outside it. It will depend upon the profile of spring used in the balloon catheter.
Since the balloon lumen is low profile it will not be any problem as during the prototype experiment I realized that since balloon will be inflated when the spring is not in compressed position, it will not matter as the low profile lumen will not be kinked at the time of balloon inflation.
Above is a cheap prototype to make sure that the concept will work

Note it is during such pushing systems I observed following problems

(A) If in monorail type balloon (rapid exchange) system if wire is out prior to spring then sometimes spring tends to buckle in guide cath and thus I wrote in specification that spring will be in part of balloon with guide wire.

(B) Wire sometimes comes out through spring thus I wrote about guide wire receptacle in original application,(though I feel not required as when I loaded guide wire in spring compressed position the problem was automatically solved)

(C) If spring came out from guiding cath before crossing the lesion, it tended to angulate and thus may cause dissection/endothelial injury in normal segment prior to obstructive lesion thus I wrote in application that it will be supplied in 2 lengths.

(D) Long nose made use of device easier thus I wrote about longer nose.

Above four observations, mentioned in application, were after above prototype use.

I did not mention about this crude prototype experiment in initial application as I did not consider it necessary.
Note I am an interventional cardiologist and it is our nature to write concise and brief notes otherwise patient's file will become unnecessary thick.

Drawing changes
Since earlier drawing changes were taken as addition to specification as fig 1 was split into 3 parts